PROPOSITION

PRESTIGE INSTITUTE OF MANAGEMENT & RESEARCH, INDORE

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(Clinical Course - IV)

Memorial Making Assignment

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SCARLATINA MEDICAL ASSOCIATION (SCMA) V. UNION OF SCARLATINA

1. Scarlatina is a developing country situated in the continent of Asia. It is densely populated and is currently the most populous country in the world. The vast land extent of the country plays host to various geographical areas such as a desert in the west, alpine tundra and glaciers in the north, and humid tropical regions supporting rainforests in the southwest and the island territories in the south. Scarlatina's climate mirrors its geographical diversity. The majority of the country experiences a tropical climate with the interior regions displaying a blend of wet and dry tropical weather, while the northern parts show a humid tropical climate andsub-zero cold climate in the alpine regions.

2. Scarlatina has always been highly susceptible to climate-related health risks due to the majorly humid and tropical climate in the country. This coupled with the high population of the country resulted in the rampant spread of infectious diseases such as dengue, tuberculosis, malaria, HIV etc. These diseases also increased the mortality rate in the country. The country had been working towards uplifting the socio-economic status of its citizens since its independence, but income inequality and significant poverty plagued the country for many decades. At its earlystage, the pharmaceutical industry in Scarlatina was heavily dependent on imports and multinational corporations held patent for most of the drugs available in the country. This resulted in high cost of essential medicines and due to lack of affordability and access to lifesaving drugs to the general population, there was significant death rate from communicable diseases.

3. The Government of Scarlatina made constant efforts to improve the public health situation in the country. In 1960s, it recognized that imported drugs proved to be expensive and unaffordable for the general population of Scarlatina. Hence, it began encouraging the growthof drug manufacturing by local companies. It enacted a series of policies designed to foster self-sufficiency in the production of basic drugs by lowering the entry barriers.

4. Further, the introduction of The Scarlatina Patent Act, 1970 (ScPA) which permitted both product and process patents, allowed the pharmaceutical sector to become less reliant on intellectual property of developed countries. This aided in the growth of numerous small-scale pharmaceutical companies in the country. It ended Scarlatina's dependence on expensive foreign drugs; fostered the development of a competitive pharmaceutical industry and guaranteed the public access to inexpensive drugs. By 1990, Scarlatina began exporting pharmaceuticals to foreign countries. The growth in healthcare ensured that the country was able to eradicate

diseases such as Polio and Smallpox completely.

5. Today, the Scarlatinian pharmaceutical industry accounts for 60% of global vaccine production and ranks worldwide for pharmaceutical production by volume. It exports pharmaceuticals to more than 190 countries. During the COVID-19 pandemic, it proved to be a reliable healthpartner and lived up to its tag of 'Pharmacy of the world' by manufacturing and exporting vaccines and other emergency medications.
6. Scarlatina's rich and ancient heritage reflects in the various kinds of alternative and indigenous medicine systems present in the country. There are over 15 alternative medicine systems of which Ayurveda and Homeopathy are the most famous. These forms of alternative medication are not approved at an international level as they do not have sufficient research backing and common regulations. Ayurvedic medicines are manufactured and exported outside of the country, sometimes illegally as well.
7. Scarlatina has also emerged as a popular destination for medical tourism over the years due to the reduced cost of health care and medicines. The presence of alternatives to allopathic medicine is also a lure for foreigners. Medical tourism has become a major source of incomefor the country. It has generated over USD 13 billion as revenue through medical tourism. Despite this, doctors and medical professionals have constantly claimed that the government overburdens medical professionals and pushes for generic medicine manufacturing for want of profit from medical tourism.
8. A 2006 report published by the Health Ministry of Scarlatina observed that despite the medical advancements made by the country, the rural areas and economically weaker sections of the society did not have easy access to life saving medicines. The report also suggested that the reason for the same was the profit liaison between doctors and pharmaceutical agents to prescribe medicines belonging to a particular brand. The report also observed that certain brands had the practice of evergreening their patents and thus ensuring that the price of medications remained high.

9. In 2008, the Government of Scarlatina started a campaign called "Medicine for People" which envisaged making unbranded quality medicines termed as 'generic medicines' available to poor people in the country at a reasonable and affordable price through retail outlets' setup with the help of the government. Generic medicines are considered to be an equal substitute for its branded counterpart as it has the same active ingredient. Over the years, Scarlatina became the world's largest manufacturer of generic medicines gaining an export income of over USD 25million.

Export of generic medicines began forming a considerable source of income to the country and hence, it has been noted that Scarlatinian Government has been aggressively pushing for pharmaceutical manufacturing and export. One of the steps taken by the Government to push for the prescription of generic medicines by doctors was introducing various regulations by the National Medical Council (NMC) which mandated/directed the prescription of generic drugs by doctors over branded drugs. Despite this, it was noticed thatdoctors preferred branded medication over generic medicines in Scarlatina due to various reasons.

10. To ensure affordable healthcare in the country and assure its citizens of their right to public health and access to essential medicines, the Parliament of Scarlatina formalized all the existing regulations into the Registered Medical Practitioner (Professional Conduct) Bill in September 2022, in which it made the prescription of generic drugs mandatory for doctors, along with other directives. It also stated that the medical practitioners would be penalized and their license to practice would be suspended for a period of time if they fail to prescribe generic medicines.The aim of this Bill was to ensure that medicines are more accessible to the public and deterdoctors from prescribing medication for the sake of endorsement or commission.

11. This created a huge uproar among the medical community. Scarlatina Medical Association (SCMA), a national voluntary organisation of physicians in Scarlatina protested against the Bill as they believed that it was a drastic method to ensure that doctors prescribe generic medicine. The SCMA also wrote a written representation to the Health Ministry of Scarlatina to withdraw the Bill.

12. The representation highlighted that,

i. The Bill undermines comprehensive medical care and weakens medical professionals' autonomy

ii. The government must firstly ensure the quality of all the drugs released into the market before making it mandatory to prescribe the same.

iii. There are no sufficient mechanisms in place in India to ensure that the generically manufactured drugs and alternative medicines meet the quality standards.

iv. The onus and power balance will shift from medical professionals to pharmacists thus defying the purpose of the Bill.

v. The Bill also restricts the right to trade of branded pharmaceutical companies

13. In August 2023, People's Medical Foundation (PMF) a rural healthcare NGO, shared a research publication about an incident that occurred in Angina, a state in the north of Scarlatina. Anginais

an alpine hilly terrain containing snow-capped mountains and valleys. The people in the Angina are heavily dependent on agriculture and tourism for their income. During the winter, their roads are cut off from the rest of the country, and they survive with the limited resources that are available with them. PMF works in this region to ensure that rural villages have accessto medicines and basic healthcare, especially during winters.

14. The research publication made by PMF mentioned that over 20 children had died of cough syrup poisoning in Angina in December 2022. The matter was investigated, and it was found that the children had suffered from kidney failure induced by a generic cough syrup that was purchased over the counter from a local pharmacy. The report also mentioned that due to the Government's push for generic medicines, the pharmacist had sold only generic cough syrupsin that locality. PMF claimed that sufficient action was not taken against the manufacturers ofthe cough syrup and the pharmaceutical companies that marketed and distributed it. The manufacturers and marketers of the said cough syrup absolved themselves of any liability by claiming that despite all efforts taken by them in manufacturing, transporting, and storing the cough syrup, the climatic conditions of Angina had rendered the medication unstable. The PMF article also pointed out that WHO had made a link between Scarlatina-made generic cough syrups to acute kidney injury in children and 66 deaths in the small West African nation of Gambia and 19 deaths in Uzbekistan in 2022.

15. Scarlatina refuted all such allegations and claimed that there was no connection between the incidents. They claimed that there was no sufficient proof to connect the deaths that occurredin different countries to the sale of generic cough syrups from Scarlatina. They further claimed that there were sufficient safeguards in place to ensure quality of medicines. Internally, in August2023, the Drugs Controller General of Scarlatina ordered the State Drugs Authorities to conduct investigations to determine whether the generic cough syrups (manufactured by Scarlatina-based manufacturers) which were exported to Gambia and Uzbekistan, were of standard quality or not. These investigations are currently ongoing. On 20th September 2023,the Registered Medical Practitioner (Professional Conduct) Act, 2023 (Appendix-I) was passed by the Parliament of Scarlatina.

16. On 15th October 2023, the SCMA filed a Public Interest Litigation before the Supreme Court challenging the constitutional validity of the Registered Medical Practitioner (Professional Conduct) Act, 2023.

17. The matter has been posted for hearing on 2nd and 3rd of February 2024 for the following questions:-

i. *Whether the parliament of Scarlatina has the legislative competence to pass the Registered Medical Practitioner (Professional Conduct) Act, 2023.*

ii. *Whether the provisions of the Registered Medical Practitioner (Professional Conduct) Act, 2023 are violative of Article 21 of the Constitution of Scarlatina.*

iii. *Whether the directions to prescribe generic medicine violates a doctor's right to exercise their independent medical judgement and freely practice their profession under Article 19(1)(g) of the Constitution.*

iv. *Whether the mandate to prescribe generic medicine is violative of the right of non-generic drug manufacturers guaranteed under Article 14 and 19(1)(g) of the Constitution of Scarlatina.*

APPENDIX- I

Note 1: The following are certain relevant excerpts from the Registered Medical Practitioner (Professional Conduct) Act, 2023. The provisions of the National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023 (New Delhi, India, 2nd August, 2023) are in pari materia with the Scarlatinian Registered Medical Practitioner (Professional Conduct) Act, 2023. The participants are free to refer to the various provisions of the said Regulations for the purpose of arguments.

Registered Medical Practitioner(Professional Conduct) Act, 2023

An Act to ensure affordable healthcare and services for people and for laying down standards of professional conduct, etiquette and code of ethics to be observed by registered medical practitioners and for matters connected therewith or incidental thereto

8. **Prescribing Generic Medicines:**

Every RMP should prescribe drugs using generic names written legibly and prescribe drugs rationally, avoiding unnecessary medications and irrational fixed-dose combination tablets.

9. **Prohibition of Fee Splitting/Commissions:**

A RMP shall not directly or indirectly participate in any act of division, transfer, assignment, subordination, rebating, splitting, or refunding of any fee for diagnostic, scanning, medical, surgical, or other treatment. These provisions shall apply with equal force to the referring, recommending, or procuring by a RMP of any patient, specimen, or material for diagnostic purposes or other studies/work. However, nothing in this section shall prohibit payment of salaries by a qualified RMP to another duly qualified person rendering medical care under his/her supervision. RMP shall not use online forums or agents for procuring patients.

10. **Prohibition of endorsement of a product or person:**

RMP individually or as part of an organization/association/society etc. shall not give to any person or to any company or to any product or to software/platforms, whether for compensation or otherwise, any medicine, nostrum remedy, surgical, or therapeutic article, apparatus or appliance or any commercial product or article with respect to any property, qualityor use thereof or any test, demonstration or trial thereof, for use in connection with his name, signature, or photograph in any form or manner of advertising through any mode nor shall he boast of cases, operations, cures or remedies or permit the publication of report thereof through any mode.

11. Responsibility of RMP regarding the sale of drugs:

a) RMP shall not run an open shop to sell medicines prescribed by RMPs other than himselfor for the sale of medical or surgical appliances. They are allowed to sell medication onlyto his/her own patients.

b) RMP can prescribe or supply drugs, remedies, or appliances as long as there is no exploitation of the patients.

Drugs prescribed by RMP or bought from the pharmacy for a patient should explicitly state the generic name of the drug.

Chapter 5: Professional Misconduct

37. **Professional Misconduct:**

Any violation of these provisions, or other applicable Acts related to medical practice which are in force, shall constitute professional misconduct, the, National Medical Council, and the State Medical Councils are in no way precluded from considering and dealing with any other form of professional misconduct by registered medical practitioners which do not fall under any of the categories mentioned in the Act or guidelines or codes appended. RMPs bound by these provisions will not engage in any activities which violate these provisions and should not enter any employment or other contract that engages in activities in violation of any of these provisions. Conviction of RMP in cases of a cognizable offence involving moral turpitude may result in the suspension of license to practice.

Generic Medicine And Prescription Guidelines

Preamble: Scarlatina's out-of-pocket spending on medications accounts for a major proportion of public spending on health care. Further, generic medicines are 30 to 80 % cheaper than branded drugs. Hence, prescribing generic medicines may overtly bring down health care cost and improve access to quality care.

Generic medicines vs Generic names:

Generic Name: Non-Proprietary or approved name of a drug is also known as the generic name of the drug. Non-proprietary name is the name accepted by a competent scientific body/ regulatory authority.

Generic drug/medicine: A generic drug is defined as a "drug product that is comparable to brand/reference listed product in dosage in dosage form, strength, route of administration, quality and performance characteristics, and intended use"

Branded Generic drug: A branded generic drug is one which has come off patent and is manufactured by drug companies and sold under different companies' brand names. These drugs may be less costly than the brandedpatent version but costlier than the bulk manufactured generic version of the drug. There is lessregulatory control over the prices of these "branded" generic drugs.

Guidance to RMPs:

1. Prescribe drugs with "generic"/ "non-proprietary"/ "pharmacological" names only
   1.1. In the case of drugs with a narrow therapeutic index, biosimilars, and similarother exceptional cases, this practice can be relaxed.
2. Prescribe drugs rationally and optimally
   2.1. Both overprescribing and underprescribing are to be avoided keeping in mind possible drug interactions
   2.2. Fixed-dose combinations are to be used judiciously
   2.3. Only approved and rational fixed-dose combinations are to be prescribed
   2.4. Advocate for hospitals and local pharmacies to stock generic drugs. Prescribe only those generic medicines that are available in the market and accessible to the patient
   2.5. Avoid prescribing "branded" generic drugs.
   2.6. Encourage patients to purchase drugs from generic pharmacy outlets
   2.7. Educate medical students, patients, and the public regarding the equivalence of generic medicine with their branded counterparts
   2.8. Should actively participate in programs related to promotion and access to generic medicines
   2.9. MBBS & PG students will be trained in the value of prescribing generic medicine
   2.10. Written Prescriptions should be legible and preferably in full CAPITALS to avoid misinterpretation. As far as possible prescriptions should be typed and printed to avoid errors.

3. **<u>NOTE 2</u>: The laws and precedents in Scarlatina are in pari material with the laws and precedents of India.**

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